STATE OF NEW YORK

4513

2023-2024 Regular Sessions

IN SENATE

February 9, 2023

Introduced by Sen. FERNANDEZ -- read twice and ordered printed, and when printed to be committed to the Committee on Health

AN ACT to amend the public health law, in relation to preserving access to affordable drugs

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Article 2-A of the public health law is amended by adding a new title IV to read as follows:

TITLE IV

PRESERVING ACCESS TO AFFORDABLE DRUGS

§ 282. Definitions. For the purposes of this title, the following terms shall have the following meanings:

1. "ANDA" shall mean abbreviated new drug application as described by 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 335(j).

2. "ANDA filer" shall mean a party that owns or controls an ANDA filed with the federal food and drug administration or has the exclusive rights under that ANDA to distribute the ANDA product.

3. "Agreement" shall mean anything that would constitute an agreement under state law.

4. "Agreement resolving or settling a patent infringement claim" includes any agreement that is entered into within thirty days of the resolution or the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim. This shall include, but is not limited to, the following:

(a) Any agreement required to be provided to the federal trade commission or the antitrust division of the United States Department of Justice under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173;

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

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(b) Any agreement between a biosimilar or interchangeable product applicant and a reference product sponsor under the Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, that resolves patent claims between the applicant and sponsor.

5. "Biosimilar biological product application filer" shall mean a party that owns or controls a biosimilar biological product application filed with the federal food and drug administration pursuant to section 351(k) of the Public Health Service Act, 42 U.S.C. 262(k), for licensure of a biological product as biosimilar to, or interchangeable with, a reference product, or that has the exclusive rights under the application to distribute the biosimilar biological product.

6. "NDA" shall mean a new drug application.

7. "Nonreference drug filer" shall mean either:

(a) An ANDA filer;

(b) A company that seeks an abbreviated approval pathway for its drug product under 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(b)(2); or

(c) A biosimilar biological product application filer, or company seeking FDA approval for a biosimilar under 42 U.S.C. 262.

8. "Nonreference drug product" shall mean the product to be manufactured under an ANDA or an application filed under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(b), that is the subject of the patent infringement claim, a biosimilar biological product that is the product to be manufactured under the biosimilar biological product application that is the subject of the patent infringement claim, or both.

9. "Patent infringement" shall mean infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition, and extensions thereof.

10. "Patent infringement claim" shall mean any allegation made to a nonreference drug filer, whether or not included in a complaint filed with a court of law, that its nonreference drug product or application infringes any patent held by, or exclusively licensed to, the reference drug holder.

11. "Reference drug holder" shall mean either:

(a) A brand holder that is any of the following:

(i) The holder of an approved NDA for a drug product application filed under section 505(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(b);

(ii) A person owning or controlling enforcement of the patent listed in the approved drug products with therapeutic equivalence evaluations in connection with the NDA; or

(iii) The predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with, any of the entities described in subparagraph (i) or (ii) of this paragraph, with control to be presumed by direct or indirect share ownership of fifty percent or greater, as well as the licensees, licensors, successors, and assigns of each of those entities; or

(b) A biological product license holder, which shall mean any of the following:

(i) The holder of an approved biological product license application for a biological drug product under section 351(a) of the Public Health Service Act, 42 U.S.C. 262(a);

(ii) A person owning or controlling enforcement of any patents that claim the biological product that is the subject of the approved biological patent license application; or

(iii) The predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with, any of the entities described in subparagraph (i) or (ii) of this paragraph, with control to be presumed by direct or indirect share ownership of fifty percent or greater, as well as the licensees, licensors, successors, and assigns of each of those entities.

12. "Reference drug product" shall mean the product to be manufactured by the reference drug holder and includes both branded drugs of the NDA holder and the biologic drug product of the biologic product license applicant.

13. "Statutory exclusivity" shall mean those prohibitions on the approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E), section 527 or section 505A of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(c)(3)(E), on the licensing of biological product applications under section 262(k)(7) of Title 42 of the United States Code or section 262(m)(2) or (3) of Title 42 of the United States Code.

§ 283. Preserving access to affordable drugs. 1. (a) Except as provided in paragraph (c) of this subdivision, an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product, shall be presumed to have anticompetitive effects and shall be a violation of this section if both of the following apply:

(i) A nonreference drug filer receives anything of value from another company asserting patent infringement, including, but not limited to, an exclusive license or a promise that the brand company will not launch an authorized generic version of its brand drug; and

(ii) The nonreference drug filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the nonreference drug filer's product for any period of time.

(b) As used in subparagraph (i) of paragraph (a) of this subdivision, "anything of value" shall be interpreted broadly to include any type of consideration, value or benefit a reference drug holder or nonreference drug filer could possibly obtain from the agreement. "Anything of value" shall not include a settlement of patent infringement claims in which the consideration granted by the reference drug holder to the nonreference drug filer as part of the resolution or settlement consists of only one or more of the following:

(i) The right to market the competing product in the United States before the expiration of either:

(A) A patent that is the basis for the patent infringement claim; or

(B) A patent right or other statutory exclusivity that would prevent the marketing of the drug;

(ii) A covenant not to sue on a claim that the nonreference drug product infringes a United States patent;

(iii) Compensation for saved reasonable future litigation expenses of the reference drug holder but only if both of the following are true:

(A) The total compensation for saved litigation expenses is reflected in budgets that the reference drug holder documented and adopted at least six months before the settlement; and

(B) The compensation shall not exceed the lower of the following:

(1) Seven million five hundred thousand dollars; or

(2) Five percent of the revenue that the nonreference drug filer projected or forecasted it would receive in the first three years of sales of its version of the reference drug documented at least twelve months before the settlement. If no projections or forecasts are available, the compensation shall not exceed two hundred fifty thousand dollars;

(iv) An agreement by the reference drug holder not to interfere with the nonreference drug filer's ability to secure and maintain regulatory approval to market the nonreference drug product or an agreement to facilitate the nonreference drug filer's ability to secure and maintain regulatory approval to market the nonreference drug product; or

(v) An agreement resolving a patent infringement claim in which the reference drug holder forgives the potential damages accrued by a nonreference drug filer for an at-risk launch of the nonreference drug product that is the subject of that claim.

(c) Parties to an agreement are not in violation of paragraph (a) of this subdivision if they can demonstrate by clear and convincing evidence that either of the following are met:

(i) The value received by the nonreference drug filer described in subparagraph (i) of paragraph (a) of this subdivision is a fair and reasonable compensation solely for other goods or services that the nonreference drug filer has promised to provide; or

(ii) The agreement has directly generated procompetitive benefits and the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

2. In determining whether the parties to the agreement have met their burden under paragraph (c) of subdivision one of this section, a court of competent jurisdiction shall not consider any of the following:

(a) That entry into the marketplace could not have occurred until the expiration of the relevant patent exclusivity or that the agreement's provision for entry of the nonreference drug product before the expiration of any patent exclusivity means that the agreement is procompetitive within the meaning of subparagraph (ii) of paragraph (c) of subdivision one of this section;

(b) That any patent is enforceable and infringed by the nonreference drug filer in the absence of a final adjudication binding on the filer of those issues;

(c) That the agreement caused no delay in entry of the nonreference drug filer's drug product because of the lack of Federal Food and Drug Administration (FDA) approval of that or of another nonreference drug product; or

(d) That the agreement caused no harm or delay due to the possibility that the nonreference drug filer's drug product might infringe some patent that has not been asserted against the nonreference drug filer or that is not subject to a final and binding adjudication on that filer as to the patent's scope, enforceability, and infringement.

3. In determining whether the parties to the agreement have met their burden under paragraph (c) of subdivision one of this section, a court of competent jurisdiction shall presume that the relevant product market is that market consisting of the reference drug of the company alleging patent infringement and the drug product of the nonreference drug filer accused of infringement and any other biological product that is licensed as biosimilar or is an AB-rated generic to the reference product.

4. (a) This section shall not modify, impair, limit, or supersede the applicability of the antitrust laws of the state pursuant to article

twenty-two of the general business law, unfair competition laws of the state pursuant to article twenty-two-A of the general business law or the availability of damages or remedies provided therein. This section shall not modify, impair, limit, or supersede the right of any drug company applicant to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition of the federal antitrust law or state law.

(b) If any provision of this subdivision, an amendment made to this subdivision, or the application of any provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this subdivision, the amendments made to this subdivision, and the application of the provisions of this subdivision or amendments to any person or circumstance shall not be affected.

5. (a)(i) Each person that violates or assists in the violation of this section shall forfeit and pay to the state a civil penalty sufficient to deter violations of this section, as follows:

(A) If the person who violated this section received any value due to that violation, an amount up to three times the value received by the party that is reasonably attributable to the violation of this section, or twenty million dollars, whichever is greater; or

(B) If the violator has not received anything of value as described in this subparagraph, an amount up to three times the value given to other parties to the agreement reasonably attributable to the violation of this section, or twenty million dollars.

(C) For purposes of this subdivision, "reasonably attributable to the violation" shall be determined by the state's share of the market for the brand drug at issue in the agreement.

(ii) Any penalty described in subparagraph (i) of this paragraph shall accrue only to the state and shall be recovered in a civil action brought by the attorney general in its own name, or by any of its attorneys designated by it for that purpose, against any party to an agreement that violates this section.

(b) Each party that violates or assists in the violation of this section shall be liable for any damages, penalties, costs, fees, injunctions, or other equitable or legal remedies, including, but not limited to, restitution and disgorgement, that may be just and reasonable. Such remedies shall include, but not be limited to, any remedy available under articles twenty-two or twenty-two-A of the general business law and section sixty-three of the executive law.

(c) If the state is awarded penalties under subparagraph (i) of paragraph (a) of this subdivision, it shall not recover penalties pursuant to another law identified in paragraph (b) of this subdivision. This section shall not be construed to foreclose the state's ability to claim any equitable or legal remedy available in paragraph (b) of this subdivision.

(d) An action to enforce a cause of action for a violation of this section shall be commenced within six years after the cause of action accrued.

§ 2. Severability clause. If any clause, sentence, paragraph, subdivision, section or part of this act shall be adjudged by any court of competent jurisdiction to be invalid or unenforceable, such judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, subdivision, section or part thereof directly involved in the controversy in which such judgment shall have been rendered. It is hereby declared to

be the intent of the legislature that this act would have been enacted even if such invalid provisions had not been included herein.

§ 3. This act shall take effect on the sixtieth day after it shall have become a law.